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Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)				
Office Action Summary		10/749,099	MIHAI ET AL.				
		Examiner	Art Unit				
		ROBERT SOREY	3626				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)[\]	Responsive to communication(s) filed on <u>24 Ma</u>	arch 2010					
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٥/١	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
	closed in accordance with the practice under L.	x parte quayre, 1000 O.D. 11, 40	0.0.210.				
Dispositi	on of Claims						
4)🛛	☑ Claim(s) <u>1-15,17-19 and 21-28</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.						
6)🖂	☑ Claim(s) <u>1-15, 17-19, and 21-28</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8)□	Claim(s) are subject to restriction and/or	election requirement.					
Applicati	on Papers						
9)□	The specification is objected to by the Examine	r.					
-	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
.—	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
2) Notic 3) Inforr	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	nte				

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DETAILED ACTION

Status of Claims

1. In the amendment filed 03/24/2010, the following occurred: claims 1, 15, 18, and 24 were amended. Claims 1-15, 17-19, and 21-28 are presented for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15, 17-19, and 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 15, 18, and 24 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As per claim 1, Applicant claims "wherein the plurality of medical devices communicate directly with the hub, and the portable remote user interface and the hub communicate directly with the first central computer", but the specification (see Figure 1 and Figure 3 of Applicant's specification) show that the portable remote user interface communicates directly with the hub – not the first central computer. Applicant's specification seems to support that both the plurality of medical devices and the portable remote user interface communicate directly with a hub which, in turn, communicates with the first central computer. Claims 15, 18, and 24 are rejected similarly.

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4. Claims 2-14, 17, 19, and 21-23, and 25-28 are rejected for similar reasons as above.

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- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claims 1-15, 17-19, and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 7. As per claim 1, Applicant teaches "wherein the plurality of medical devices communicate directly with the hub, and the portable remote user interface and the hub communicate directly with the first central computer". It is unclear as to if the portable remote user interface is communicating with the first central computer directly or via the hub. Claims 15, 18, and 24 are rejected for similar reasons.
- 8. As per claim 24, Applicant teaches "the second non-validation portion of the central computer sharing a server with the central validation portion and separated from the central validation portion by a logical separation or firewall", but is unclear as to what Applicant means by "logical separation" how does is differ from a firewall? It is also unclear as to how this logical separation or firewall functions and is being used firewalls between databases govern access to networked computer systems, which is only tangentially a separation of data as firewalls are generally detached from the data that is behind them.
- 9. Claims 2-14, 17, 19, and 21-23, and 25-28 are rejected for similar reasons as above.

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Nonfunctional Descriptive Material

10. As per claims 1-6, 15, 18, and 24, the Examiner has placed little weight on the functional feature sets and the data types since the effect of said feature sets and data types on the claimed system and method was not made clear in the claims and did not effect or alter the claimed invention. Therefore, the functional feature sets and data types in the cited claims are nonfunctional descriptive material and are given little weight for the purposes of examination. The Examiner has cited portions of the prior art that read on the nonfunctional descriptive material in the claims where convenient. See: Ex parte Herman Mathias, Appeal No. 2005-1851, Application No. 09/612788; and Ex parte James Prescott Curry, Appeal No. 2005-0509, Application No. 09/449237.

Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 12. Claims 1-11, 13-15, 17-19, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned in view of U.S. Patent Application Publication 2003/0084024 to Christensen in view of U.S. Patent 6,360,211 to Anderson further in view of U.S. Patent 5,953,706 to Patel.
- 13. As per claim 1, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

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--a plurality of medical devices (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--a hub connected to (i) the plurality of medical devices and (ii) a first central computer (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the first central computer having a first database (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) and a first functional feature set associated with data and functions related to the plurality of medical devices (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), wherein the plurality of Art Unit: 3626

medical devices <u>communicate directly with the hub and the hub</u> communicate directly with the first central computer_(Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless);

--a second central computer having a second database (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632) and a second functional feature set (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), wherein the first central computer is securely connected to the second central computer, wherein the plurality of medical devices do not communicate directly with the second central computer (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server).

As per the limitation:

--a portable remote user interface; and subsequent teachings of the portable remote user interface communicating directly with the first central computer, and including wherein the portable remote user interface can receive data from the second

database relating to the second functional feature set of the second central computer through the first central computer.

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

As per the limitation:

--wherein the first database is a subset of the second database

De La Huerga ostensibly teaches the limitation by stating that the server archives all standing infusion orders (see: De La Huerga, paragraph 243); however, addressing the alternative situation in which De La Huerga does not teach said limitation with the desired configuration, the limitation is rejected here further in view of Christensen's teachings of a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database (see: Christensen, paragraph 61).

As per the limitation:

--the second central computer sending a signal to the first central computer at designated time intervals causing the subset of data in the first database to synchronize with the corresponding data in the second database, and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs at designated time intervals; however, Anderson teaches synchronizing databases on a periodic basis (see: Anderson, column 7, lines 40-48).

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As per the limitation:

--when critical information in the second database changes which is also part of
the first database, causing the information to be relayed immediately to and processed
by the first central computer; and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs immediately and automatically when information in a database changes; however, Patel teaches synchronizing databases immediately and automatically with any change in information (see: Patel, column 6, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Christensen, Anderson, and Patel. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the

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same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

14. As per claim 2, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

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--the first functional feature set comprises at least one of a volumetric infusion pump feature (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), and a syringe pump feature (see: De La Huerga, paragraph 330, is met by syringe injectors).

15. As per claim 3, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

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--the first functional feature set comprises at least one of a change pump channel feature, an administer infusion feature (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), a stop or discontinue infusion feature (see: De La Huerga, paragraph 150-152, 167, 173, 208, 210, 279, and 322, is met by delivery parameters adjustment, including duration, and "OFF" and "discontinue" options; and "stop and start" buttons), a resume infusion feature, and a remove pump feature.

16. As per claim 4, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the second functional feature set comprises at least one of a patient management feature, an item management feature, a facility management feature, a

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messaging feature (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), an alarms/alerts feature (see: De La Huerga, paragraphs 211, 243, is met by alert activator, and indicator activation), a billing interface feature (see: Bocioned, paragraph 19, is met by insurance and billing information accessible with remote devices including a palmtop), a formulary interface feature, a lab results interface feature, an inventory tracking feature, a clinician administration feature, an order entry feature, a pharmacy feature, a user interface feature, a user interface and clinician association feature, a volumetric infusion pump feature, and a syringe pump feature.

17. As per claim 5, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the first database comprises at least one of pump data (see: De La Huerga, paragraph 151, 152, 167, 208, 210, 273, and 322, is met by delivery parameters), pump channel data, pump sub-channel data, order data, clinician data (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that

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infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), patient data, user interface data, medical device data, hub data, titration data, comparison data, alarm data, escalation data, hub alarm data, pump alarm data, channel alarm data, and alarm history data.

18. As per claim 6, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the second database comprises at least one of patient management data (see: De La Huerga, paragraphs 192, 199, and 200, is met by memory with stored patient ID), item management data, facility management data, messaging data (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), alarms/alerts data, inventory tracking data, a clinician administration data, order entry data, user interface and clinician association data.

19. As per claim 7, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

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--the first central computer is operably connected to the second computer through at least one of a dedicated TCP/IP hard-wired connection, a high speed, low latency virtual private network, and a public or shared infrastructure utilizing encryption through a fiber optic connection, a microware connection, or a high speed wireless connection (see: De La Huerga, paragraphs 149, 194, 195, and 273, is met by wireless connections).

20. As per claim 8, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the second central computer sends data from the second database to the first central computer in a first standard protocol, and the first central computer sends the data to the portable remote user interface in a second standard protocol (see: De La Huerga, paragraphs 145-151, 194, 195, and 211, is met by the plurality of protocols including: an Internet protocol, Bluetooth protocol, and IRDA protocol).

21. As per claim 9, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the second central computer sends second data from the second database to the first central computer, wherein the first central computer combines the second data with first data from the first database with the second data, and wherein the first central computer sends the combined fist and second data to the portable remote user interface for display on a display of the user interface (see: De La Huerga, paragraph 149-151, 211, 285, and 289-291, is met additional patient information obtained from remote facility server and displayed on interface screen; is met by the controller

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activating an indicator, or alert displaying patent's name, on the interface via the infusion controller; and is met by altering infusion status parameters displayed on the user interface with data entered at the controller or infusion controller).

22. As per claim 10, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--a plurality of wireless access points through which the plurality of medical devices and the portable remote user interface communicate with the first central computer (see: De La Huerga, paragraph 41, 89, 273, and 322, is met by pump in wireless communication with the transceiver - i.e. hub - at the controller).

23. As per claim 11, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the first central computer receives second data from the second database in the second central computer for use in a validation procedure (see: De La Huerga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller; and paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

24. As per claim 13, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

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--the first central computer receives data from at least one of the portable remote user interface (see: Bocioned, paragraphs 17-21) and the plurality of medical devices (see: De La Huerga, paragraph 277, controller used to control virtually all aspects of pump operation and monitoring),

--and determines whether the received data is valid in order to enable the first central computer to perform a further step (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark).

25. As per claim 14, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

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--the first central computer sends operation data from at least one of the first database and the second database to the plurality of medical devices for use in the operation of the plurality of medical devices (see: De La Huerga, paragraphs 243, 259, 260, and 268-271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

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26. As per claim 15, De La Huerga teaches a method for operating a healthcare system in a care-giving facility having a *plurality of* medical *devices*, a *portable remote* user interface, a first central computer securely connected to a second central computer having a second database <u>including second data</u>, the method comprising the steps of:

--the first central computer receiving medical data directly from a plurality of medical devices through a hub connected to the plurality of medical devices, the hub connected to the first central computer (Fig. 26, ele. 100a, 100b, and 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, medical devices are met by IV pumps 100a and 100b and hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the first central computer securely receiving the second data from the second database (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), wherein the plurality of medical devices are configured to not

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communicate directly with the second central computer (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server);

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--the first central computer utilizing a first functional feature set to process at least one of the first data (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark) and the second data.

As per the limitation:

--the first central computer receiving user data directly from the portable remote user interface; and subsequent teachings of the portable remote user interface connected to the hub and being configured not to communicate with the second central computer,

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

As per the limitation:

Stating that the first data from the first database, which is a subset of the second data

De La Huerga ostensibly teaches the limitation by stating that the server archives all standing infusion orders (see: De La Huerga, paragraph 243); however, addressing the alternative situation in which De La Huerga does not teach said limitation with the desired configuration, the limitation is rejected here further in view of Christensen's teachings of a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database (see: Christensen, paragraph 61).

As per the limitation:

--the first central computer retrieving first data from a first database, the second central computer sending a signal to the first central computer at designated time intervals causing the subset of data in the first database to synchronize with the corresponding data in the second database, and

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De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs at designated time intervals; however, Anderson teaches synchronizing databases on a periodic basis (see: Anderson, column 7, lines 40-48).

As per the limitation:

--when critical information in the second database changes which is also part of the first database, causing the information to be relayed immediately to and processed by the first central computer

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs immediately and automatically when information in a database changes; however, Patel teaches synchronizing databases immediately and automatically with any change in information (see: Patel, column 6, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Christensen, Anderson, and Patel. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the

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same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

27. As per claim 17, De La Huerga teaches the invention substantially as claimed, see discussion of claim 15, and further teaches:

--providing for sending the second data to the portable remote user interface from the first central computer (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication; and Bocioned, paragraphs 17-21).

28. As per claim 18, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

--a plurality of medical devices (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--a hub connected to (i) the plurality of medical devices and (ii) a central validation computer (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the central validation computer having a validation database (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) and a first functional feature set associated with data and functions related to the plurality of medical devices (see: De La Huerga, paragraph 208, is met by controller

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controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), wherein the plurality of medical devices communicate directly with the hub, and the hub communicate directly and securely with the central validation computer (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless);

--a second central computer having a second database and a secure connection with the central validation computer (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), and a second functional feature set

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(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), wherein the plurality of medical devices and the portable remote user interface are configured to not communicate directly with the second central computer (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server), and.

As per the limitation:

--a portable remote user interface; and subsequent teachings of the portable remote user interface communicating directly and securely with the central validation computer, and including wherein the portable remote user interface receives data from the second database relating to the second functional feature set of the second central computer through the central validation computer.

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

As per the limitation:

--wherein the validation database is a subset of the second database

De La Huerga ostensibly teaches the limitation by stating that the server archives all standing infusion orders (see: De La Huerga, paragraph 243); however, addressing the alternative situation in which De La Huerga does not teach said limitation with the desired configuration, the limitation is rejected here further in view of Christensen's teachings of a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database (see: Christensen, paragraph 61).

As per the limitation:

--the second central computer sending a signal to the central validation computer at designated time intervals causing the data in the validation database to synchronize with the corresponding data in the second database, and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs at designated time intervals; however, Anderson teaches synchronizing databases on a periodic basis (see: Anderson, column 7, lines 40-48).

As per the limitation:

--when critical information in the second database changes with is also part of
the validation database, causing the information to be relayed immediately to and
processed by the central validation computer

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De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs immediately and automatically when information in a database changes; however, Patel teaches synchronizing databases immediately and automatically with any change in information (see: Patel, column 6, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Christensen, Anderson, and Patel. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

- 29. As per claim 19, De La Huerga teaches the invention substantially as claimed, see discussion of claim 18, and further teaches:
- --the central validation computer is securely connected to the second computer computer (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server).
- 30. As per claim 21, De La Huerga teaches the invention substantially as claimed, see discussion of claim 18, and further teaches:
- --the central validation computer receives second data from the second database in the second central computer for use in a validation procedure performed by the

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central validation computer (see: De La Huerga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller; and paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

31. As per claim 23, De La Huerga teaches the invention substantially as claimed, see discussion of claim 21, and further teaches:

--wherein central validation computer receives first data from at least one of the portable remote user interface and the plurality of medical devices (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller

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automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), and

--wherein the validation procedure comprises the step of determining whether the first data matches the second data (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

- 32. Claim 12 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga in view of U.S. Patent Application Publication 2003/0084024 to Christensen in view of U.S. Patent 6,360,211 to Anderson in view of U.S. Patent 5,953,706 to Patel further in view of U.S. Patent Application Publication 2003/0105806 to Gayle et al.
- 33. As per claim 12, De La Huerga teaches the invention substantially as claimed, see discussion of claim 11, but fails to specifically teach:

--the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, such receiving and determining of XML documents is well known in the art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Christensen,

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Anderson, Patel, and Gayle. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

34. As per claim 22, De La Huerga teaches the invention substantially as claimed, see discussion of claim 21, but fails to specifically teach:

--the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, such receiving and determining of XML documents is well known in the art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Christensen, Anderson, Patel, and Gayle et al. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

35. Claims 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned in view of U.S. Patent 6,360,211 to Anderson further in view of U.S. Patent 5,953,706 to Patel.

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36. As per claim 24, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

--a plurality of medical devices (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--a hub connected to (i) the plurality of medical devices and (ii) a central validation portion of a central computer (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the central validation portion of the central computer having a validation portion of a database (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) and a first functional feature set associated with the data and functions related to the plurality of medical devices and the portable remote user interface (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller

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used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), wherein the plurality of medical devices communicate directly with the hub, and the portable remote user interface and the hub communicate directly and securely with the central validation portion of the central computer (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless); and

--a second non-validation portion of the central computer having a second non-validation portion of the database (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632) and a second functional feature set (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), wherein the plurality of medical devices and the portable remote user interface are configured and arranged to not communicate directly with the second non-validation portion of the central computer and (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server).

As per the limitation:

--a portable remote user interface; and subsequent teachings of the portable remote user interface communicating directly and securely with the central validation computer including wherein the portable remote user interface receives data from the second non-validation portion of the database relating to the second functional feature set of the second non-validation portion of the central computer through the central validation portion of the central computer

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

As per the limitation:

--the second non-validation portion of the central computer sharing a server with
the central validation portion and separated from the central validation portion by a
logical separation or firewall

Bocioned also teaches a firewall (Fig. 1)(see: Bocioned, paragraph 19 and 20) and it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a firewall into a computer server system with the motivation of separating data and limiting data access.

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As per the limitation:

--the second non-validation portion of the database synchronizing with the validation portion of the database at designated time intervals, and

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs at designated time intervals; however, Anderson teaches synchronizing databases on a periodic basis (see: Anderson, column 7, lines 40-48).

As per the limitation:

--when critical information in the second non-validation portion of the database changes, the critical information being relayed immediately to the validation portion database.

De La Huerga teaches the controller utilizing a transponder to communicate information to the processor and memory (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195) but does not specifically teach said limitation wherein synchronization of the databases occurs immediately and automatically when information in a database changes; however, Patel teaches synchronizing databases immediately and automatically with any change in information (see: Patel, column 6, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson,

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and Patel. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

37. As per claim 25, De La Huerga teaches the invention substantially as claim, see discussion of claim 24, but fails to specifically teach:

--the central validated portion of the central computer operates in a first environment running a first operating system (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622), and the second non-validation portion of the central computer operates in a second environment running a second operating system (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632).

38. As per claim 27, De La Huerga teaches the invention substantially as claimed, see discussion of claim 24, but fails to teach:

--the central computer is a single server (Fig. 26, ele. 260; and Fig. 26A, ele. 620 and 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622 and the processor 620 in a single controller 260).

39. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned in view of U.S. Patent

6,360,211 to Anderson in view of U.S. Patent 5,953,706 to Patel further in view of U.S. Patent Application Publication 2003/0105806 to Gayle et al.

40. As per claim 26, De La Huerga teaches the invention substantially as claimed, see discussion of claim 25, but fails to specifically teach:

--the first and second operating systems are separated by a fire wall.

However, such firewalls are well known in the art as evidenced by Gayle et al. (Fig. 1, ele. 136)(see: Gayle et al., paragraph 22 and 37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson, Patel, and Gayle et al. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

41. As per claim 28, De La Huerga teaches the invention substantially as claimed, see discussion of claim 24, and further teaches:

--the central computer comprises a first server (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) and a second separate server (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), wherein the central validation portion of the central computer resides in the first server (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to

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the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), wherein the plurality of medical devices communicate directly with the first central computer (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless), and wherein the second non-validation portion of the central computer resides on the second server (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

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Fails to specifically teach:

--the first and second servers being separated by a fire wall

However, such firewalls are well known in the art as evidenced by Gayle et al.

(Fig. 1, ele. 136)(see: Gayle et al., paragraph 22 and 37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Anderson, Patel, and Gayle et al. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

- 42. **Claim 27** is rejected again under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned in view of U.S. Patent 6,360,211 to Anderson further in view of U.S. Patent 5,953,706 to Patel.
- 43. As per claim 27, De La Huerga teaches the invention substantially as claimed, see discussion of claim 24, but fails to teach:
 - --the central computer is a single server.

However, that the central computer is composed of a single server instead of a plurality of servers is merely a matter of obvious design choice (see: MPEP, Chapter 2144.04, part B, Making Integral).

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Response to Arguments

44. Applicant's arguments from the response filed on 08/13/2009 have been fully considered and will be addressed below in the order in which they appeared.

45. In the remarks, Applicant argues in substance that (1) the 35 U.S.C. 112, second paragraph, rejections should be withdrawn in view of corrective amendments.

The rejections have been withdrawn; however, new rejections under 35 U.S.C. 112 concerning new matter and indefiniteness have arisen – see rejections above.

46. In the remarks, Applicant argues in substance that (2) rejections under 35 U.S.C. 103(a) should be withdrawn due to amendments concerning synchronization and because "De La Huerga does not disclose memory 622 being synchronized with data in memory of element 630 at designated time intervals, or critical information changing causing that information to be immediately relayed to communications device 620" nor does any of the other previously cited prior art.

Applicant's arguments with respect to the limitations added upon amendment have been considered but are most in view of the new ground(s) of rejection.

Conclusion

47. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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48. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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- 49. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT SOREY whose telephone number is (571) 270-3606. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM (EST).
- 50. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 51. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./ Examiner, Art Unit 3626

/Robert Morgan/ Primary Examiner, Art Unit 3626